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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,914	12/28/2001	Yoshihide Murakami	Q67950	2679

7590 04/14/2005

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EXAMINER

CHANG, VICTOR S

ART UNIT PAPER NUMBER

1771

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,914

Applicant(s)

MURAKAMI ET AL.

Examiner

Victor S. Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Introduction

1. In an interview on 3/9/2004 with attorney Louis Gubinsky, the Examiner has agreed that an error was made in an Advisory dated 2/25/2004, because the Examiner has misidentified a Preliminary Amendment to claim 1 as proposed Amendment After Final (see interview summary dated 3/17/2004). The Examiner has apologized for the inadvertent error, and agreed to reconsider the application. However, it was later discovered that the Final Office action was dated 10/3/2003, and Applicants have not made a request for continued examination under 37 CFR 1.114, the application should be abandoned. Nonetheless, after a discussion with the Examiner's supervisor, it was determined that since a proper Office action, at the time of Advisory action was made, would have been required to reopen the case, because Applicants' argument and submission of a Terminal Disclaimer dated 1/30/2004 are sufficient to overcome the prior double patenting rejections in the Final Office action, the PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

Terminal Disclaimer

2. The terminal disclaimer filed on 1/30/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 6,372,339 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bezwada et al. (US 5607687).

Bezwada's invention is directed to a bioabsorbable polymeric material and blends thereof and more particularly to absorbable surgical products made from such polymers and blends thereof (column 1, lines 11-14). The blends comprises polyether polyurethanes, polyester polyurethanes, polyvinyl pyrrolidone, etc., and combinations thereof (column 2, lines 17-67). Useful embodiments made of the polymer blend include sheets for areas where the skin and underlying tissues are damaged or surgically removed, i.e., wound dressing (column 6, lines 38-64).

For claims 1-4, 6 and 8, Bezwada is silent about the relative strength in tensile moduli of elasticity between the elastomer resin and the hydrophilic polymer. However,

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since Bezwada teaches the same elastomer resins and hydrophilic polymer (i.e., polyether polyurethanes, polyester polyurethanes, polyvinyl pyrrolidone) as the instant invention, it is the Examiner's position that, in the absence of evidence to the contrary, the relative strength in tensile moduli between the elastomer resin and the hydrophilic polymer is either anticipated by Bezwada, or obviously provided once the same polymers are selected. It should be noted that where the claimed and prior art products are shown to be identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See MPEP § 2112.01.

For claims 5 and 7, Bezwada lacks a teaching of the weight ratio between the hydrophilic polymer and the elastomer resin. However, since Bezwada does teach the same polymer blend (e.g., a blend of polyester polyurethanes/polyvinyl pyrrolidone) and for the same application (absorbable surgical products for skin contact), as set forth above, it is the Examiner's position that, in the absence of evidence to the contrary, a suitable weight ratio between the hydrophilic polymer and the elastomer resin is either anticipated Bezwada, or is obviously provided by practicing the invention of the prior art.

Similarly, for claim 9, although Bezwada is silent about the relative strength in tensile moduli between the film in a water saturated state and a dry state, since Bezwada does teach the same polymer blend (e.g., a blend of polyester polyurethanes /polyvinyl pyrrolidone) and for the same application (absorbable surgical products for skin contact), it is the Examiner's position that, in the absence of evidence to the contrary, a suitable relative strength in tensile moduli between the film in a water

saturated state and a dry state is either anticipated Bezwada, or is obviously provided by practicing the invention of the prior art.

Finally, it should be noted that in claims 1-9, the recitation "for an adhesive sheet" in the preamble has not been given patentable weight, because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause.

6. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bezwada et al. (US 5607687) in view of Webster (US 4541426).

The teachings of Bezwada are again relied upon as set forth above.

For claims 17 and 18, Bezewada lacks a teaching that a layer of an adhesive is formed on the surface of the bioabsorbable polymeric sheet. However, it is noted that Webster's invention is directed to a dressing suitable for application to lesions of the skin (i.e., wound dressing). The film consists of two layers laminated together, the first layer which is the lesion contacting layer is formed from a material which swells in contact with water (Abstract). Suitably the first layer which contacts the wet surface of the lesion will be formed from a hydrophilic polymer, such as films of blends of polyurethane with polyvinyl pyrrolidone, etc. Aptly such a hydrophilic polymer will contain between 5 and 95% by weight water when hydrated (column 2, line 49 to column 3, line 2). An adhesive may be applied over the entire surface of the first layer so that when in use the dressing is adhered to the intact skin (column 5, lines 63-65). As such, in the absence of unexpected results, it would have been obvious to one of

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ordinary skill in the art to modify Beza^{da}wa's bioabsorbable polymeric sheet with a layer of adhesive on its surface, as taught by Webster, motivated by the desire to obtain a wound dressing which can be adhered to the intact skin.

Conclusion

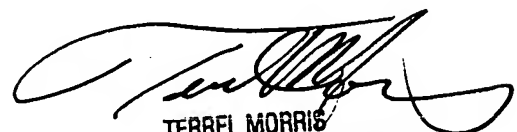
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor S Chang
Examiner
Art Unit 1771

4/8/2005


TERREL MORRIS
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